REMARKS/ARGUMENTS

Claims 1-27 remain in this application.

Claim rejections under 35 U.S.C. 112

Claims 11-13, 15 and 21-25 were rejected under 35 U.S.C. 112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner alleges that the method claims 11 and 21 fail to recite a step for detecting the labeled reagent and a correlation step that relates detected labeled reagent to the presence of analytes in a liquid sample. Solely in the interests of clarity and to further prosecution, Applicants have amended claim 11 to now include the step of detecting the presence of bound labeled reagent with the ligand-analyte pair at the test zone and has amended claim 21 to now include the step of detecting the presence of the reaction complex. Applicant asserts that these claims as presently amended would be clear to a person of ordinary skilled in the art after having read the specification.

The Examiner alleges that Claim 15 is vague as to where the absorbent sink is situated. Applicant has amended this claim to now recite "an absorbent sink provided downstream of said test zone".

Reconsideration of the objection of these claims is respectfully requested.

PAGE 11/17 * RCVD AT 10/5/2006 9:31:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/3 * DNIS:2738300 * CSID:4165957306 * DURATION (mm-ss):05-10

Claim rejections under 35 U.S.C. § 102

Claims 1, 4-6, 9-15, 18, 19, 21, 22, 24 and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by Clark et al (U.S. patent 5,526,010). The Examiner alleges that Clark et al. teaches each and every element in the instant claims. Applicant respectfully submits that the Examiner is completely incorrect in their interpretation of the Clark et al. reference and desires to traverse the rejection. Clark et al. discloses a bi-directional (reversible flow) chromatographic assay device. Applicant asserts that the device of Clark et al. includes front and rear end and an elongated flow matrix to which a fluid sample suspected of containing an analyte is applied via a sample application means. The analyte is first contacted with a non-immobilized labeled specific binding reagent and the fluid sample continues to flows along in the **forward** direction away from the sample application means where analyte then contacts an immobilized analyte capture reagent at a reactive zone. The fluid sample continues in the **forward** direction to saturate the flow matrix at which point flow ceases at the front end of the flow matrix. At the front end, is a spatially distinct liquid wash reagent reservoir containing a wash reagent and/or a detection reagent, while, at the rear end, is a spatially distinct absorbent reservoir capable of drawing fluid sample out of the matrix. When the flow matrix is brought in contact with the absorbent reservoir and the liquid wash reagent reservoir, the fluid sample in the flow matrix **reverses direction** and moves toward the absorbent reservoir. Fluid flow toward the absorbent reservoir causes the liquid wash reagent to flow by capillarity into the flow matrix in the **reverse** direction towards the absorbent reservoir at the

PAGE 12/17 * RCVD AT 10/5/2006 9:31:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/3 * DNIS:2738300 * CSID:4165957306 * DURATION (mm-ss):05-10

rear end passing through the reactive zone. Clark et al. describes the liquid wash reagents as liquid reagents that wash away unbound sample and unbound labeled specific binding reagent away from the reactive zone. The liquid wash reagent may be used in conjunction with a liquid detection reagent which facilitates analyte detection or a detection reagent alone, which can act to both wash and facilitate analyte detection. The description describes the detection reagent as "merely a wash solution" when the labeled specific binding reagent is conjugated to a radioactive, fluorescent, or light-absorbing molecule. The detection reagent is a "substrate" when the labeled specific binding reagent is an enzyme. Specifically, Applicant asserts that Clark et al. emphasizes only a bi-directional/reverse-flow device and teaches that a liquid wash reagent and/or detector reagent is required.

Contrary to Clark et al., Applicants device as claimed is not a reverse flow device, the present invention is a unidirectional flow device, furthermore, Applicants device does not require any liquid wash reagents or liquid detection reagents. Firstly, Applicants assert that Clark et al. does not show or disclose a spatially distinct reservoir containing a labeled reagent as clearly recited in the instant claims. The instant description on page 15 clearly recites that a "reservoir" is a repository or supply of dried reagent such as a detection reagent. Also, the instant description on page 14 clearly recites that a detection reagent is a "labeled mobilizable molecule". As mentioned above, the reagent reservoir in Clark et al. is simply a liquid reservoir for storing the liquid wash and/or detection reagent. Applicant wishes to point out to the Examiner that the "labeled detection

PAGE 13/17 * RCVD AT 10/5/2006 9:31:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/3 * DNIS:2738300 * CSID:4165957306 * DURATION (mm-ss):05-10

reagent" recited on page 3, item 3 of the Office Action should probably be more appropriately be referred as being the non-immobilized labeled specific binding reagent present in the flow matrix of Clark et al.. Furthermore, Applicant asserts that there is simply no passage in Clark et al. that describes that the reagent reservoir contains a "labeled detection reagent" as alleged by the Examiner. In the present invention, when the spatially distinct reservoir containing the labeled reagent is brought into contact with a wetted chromatographic medium, resolubilization of the labeled reagent is accomplished using the wetted chromatographic medium itself and the movement of the resolubilized labeled reagent towards the absorbent sink through the test zone is driven by capillarity. Accordingly, in the present invention, no wash reagents are required. Lastly, Applicants assert that Clark et al. does not show or disclose migration of the labeled reagent from the reservoir to the absorbent sink through the test zone.

To summarize, with respect to the Examiners rejection of independent claims 1, 6, 11, 14 and 21, Applicant asserts that Clark et al. does not show or disclose each and every element in claims 1, 6, 11, 14 and 21 and therefore cannot anticipate these claims. Specifically, Clark et al. does not disclose or show "at least one spatially distinct reservoir containing a labeled reagent". As the Examiner is no doubt aware, for Clark et al. to form the basis for a rejection under 35 U.S.C. § 102(b) and anticipate the instant claims, it must contain each and every element. Accordingly, dependent claims (4 and 5), (9 and 10), (12 and 13), (15, 18 and 19) and (22 and 24) which add additional limitations to claims 1, 6 and 11, 14 and 21 respectively, also cannot be rejected for being anticipated by

PAGE 14/17 * RCVD AT 10/5/2006 9:31:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/3 * DNIS:2738300 * CSID:4165957306 * DURATION (mm-ss):05-10

Clark et al.. Applicant respectfully requests the Examiner withdraw the rejection of these claims for lacking novelty in view of Clark et al.

Claim rejections under 35 U.S.C. § 103

Claims 2, 3, 7, 8, 16, 17, 20 and 23 were rejected under 35 U.S.C. § 103 as being obvious having regard to Clark et al. in view of May et al. (WO 88/08534). The Examiner alleges that Clark et al. differs from the instant invention for failing to teach the use of colloidal gold particles as a label reagent and detection of hCG. The Examiner alleges that May et al. discloses a chromatographic test strip device for performing immunoassays which can be used to detect hCG using colloidal gold label reagents. Applicant desires to traverse the rejection. As asserted above, Clark et al. fails to disclose or show each and every element in the instant claims. The Examiner is relying on May et al. to teach the use of colloidal gold particles as a label reagent and detection of hCG. However, Applicant asserts that Clark et al. and May et al. even in combination, fails to disclose or show each and every element in the instant claims. Applicant respectfully requests the Examiner withdraw the rejection of these claims for being obvious in view of Clark et al. having regard to May et al.

Claims 26 and 27 were rejected under 35 U.S.C § 103(a) as being obvious having regard to Clark et al. in view of Foster et al. (U.S. patent 4,444,879). The Examiner alleges that Foster et al. discloses a test kit for performing immunoassays that includes instructions. Applicant desires to traverse the rejection. Similar to as asserted above, Clark et al. fails to disclose

PAGE 15/17 * RCVD AT 10/5/2006 9:31:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/3 * DNIS:2738300 * CSID:4165957306 * DURATION (mm-ss):05-10

or show each and every element in the instant claims. The Examiner is relying on Foster et al. to teach the use an immunoassay test kit that includes instructions. However, Applicant asserts that Clark et al. and Foster et al. even in combination, fails to disclose or show each and every element in the instant claims. Applicant respectfully requests the Examiner withdraw the rejection of these claims for being obvious in view of Clark et al. having regard to Foster et al.

Miscellaneous

Please be advised that Applicant has become made aware of a clerical error in claim 21. In part ii., the expression "detectable unlabelled reactant/analyte/unlabeled reactant complex" should correctly recite "detectable unlabelled reactant/analyte/labeled reactant complex". Support for this clerical amendment may be found in the specification as originally filed and that no new matter has been added. For instance, Applicant directs the Examiner attention to part i of the claim where it is recited that "...the unlabelled reactant/analyte product to form a detectable unlabelled reactant/analyte/labeled reactant complex...". Entry of the amendment is respectfully requested.

It is respectfully submitted that this amendment and response overcomes the Examiners objections and rejections to the application as originally filed. Reconsideration of the application is requested. It is respectfully submitted that the present application is in suitable condition for allowance; notice of which is requested.

PAGE 16/17 * RCVD AT 10/5/2006 9:31:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/3 * DNIS:2738300 * CSID:4165957306 * DURATION (mm-ss):05-10

If the Examiner feels that prosecution of the application can be expedited by way of an Examiner's Amendment, the Examiner is invited to contact the Applicant's attorney at the number listed below.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

SIM & MCBURNEY

By _____

Lola A. Bartoszewicz, Ph.D.
Reg. No: 43394
Tel : 416 849 8420

KKM/ LAB/ca

PAGE 17/17 * RCVD AT 10/5/2006 9:31:11 AM [Eastern Daylight Time] * SVR:USPTO-EFXRF-2/3 * DNIS:2738300 * CSID:4165957306 * DURATION (mm-ss):05-10